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10/596,468

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EXAMINER

CHEN, CATHERYNE

ART UNIT

PAPER NUMBER

1655

NOTIFICATION DATE

DELIVERY MODE

01/08/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/596,468 | Applicant(s) RICHELLE ET AL. | |
| | Examiner CATHERYNE CHEN | Art Unit 1655 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 19, 20 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-18, 21, 23-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/12/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Currently, Claims 1-26 are pending. Claims 9-18, 21, 23-26 are examined on the merits.

Election/Restrictions

Claims 1-8, 19, 20, 22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on Oct. 24, 2008.

Applicant's election with traverse of Group II (Claims 9-18, 21-26), the species hesperidine, vitamin C, human, ageing, hair gloss, skin, in the reply filed on Oct. 24, 2008 is acknowledged. The traversal is on the ground(s) that the species are linked and not exclusive of each other. This is not found persuasive because a search of one group is not coextensive with the search of the other groups. Thus, it would be burdensome to search the entire claims.

The requirement is still deemed proper and is therefore made FINAL.

Specification

Art Unit: 1655

The use of the trademarks Encompass, Promega, Eukit, RNase ZAP, Applied Biosystems, Agilent Technologies, Spectra Fluor Plus F, Eppendorf, Ambion, Q Biogene, Fluka, Molecular Probes, Invitrogen, Amersham Biosciences, Ribogreen, have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-18, 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of

Art Unit: 1655

the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and the breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Limited amount of guidance and limited number of working examples in the specification

While the Specification recited damages in the skin produced by a stress situation, no specific type of skin disorder is recited to be prevented (page 7, lines 1-4).

Nature of the invention

There are many types of skin disorders with many different causes (see Specification, page 7, lines 6-17). Thus it would be impossible to prevent someone from getting all types of skin disorders through genetic disposition, such as xeroderma pigmentosum (see <http://dermnetnz.org/systemic/xeroderma-pigmentosum.html>).

State of the prior art

There are many causes of skin disorder. It has been found that metabolic factors, such as hormonal levels; autoimmune factors that cause inflammation; mechanical injury; inherited traits that increase susceptibility; lifestyle factors, such as smoking or dirt, can cause skin disorders.

Relative skill level of those in the art

Those in the art would have a difficult time to skin disorder because of the many causes of skin disorders. Therefore, the relative skill level required would be high.

Predictability or unpredictability in the art

Because of the many causes of skin disorders, the unpredictability in the art would be high.

The breadth of the claims

The breadth of the claims is broad, particularly for preventing a skin disorder.

Applicant's claims are broadly drawn to a composition that is able to prevent a skin disorder. In order to be enabled for prevention of a condition, applicant must demonstrate that the invention is able to prevent the condition each and every instance of that condition. Applicant's specification does not set forth any evidence that the claimed product is able to prevent skin disorder for all potential causes of skin disorder. In addition, the art teaches skin disorder prevention is not accepted as possible because many risk factors such as age, race and family history cannot be controlled (see <http://dermnetnz.org/systemic/xeroderma-pigmentosum.html>). Because applicant's specification does not show prevention of skin disorder and the art acknowledges that prevention is not currently possible, a person of ordinary skill in the art would be forced to experiment unduly in order to determine if applicant's invention actually functions as claimed. Therefore, the claims are not considered enabled for the prevention of skin disorders.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 9, the term “improving” is subject to interpretation; thus, what is an improvement is indefinite. Please correct and define.

Claims 9-15 are indefinite because it is not clear what is exactly encompassed by “derivative” of flavanones. Page 3 of applicant’s specification gives a list of flavanone derivatives but only states that the list is possible examples of derivatives. Since applicant’s definition of “derivative” is opened ended, what is encompassed by “derivative” cannot be definitely determined. Numerous compounds could possibly be derived from flavanone including simple elements like carbon and hydrogen. It is not clear what compounds would still be considered “derivatives” in keeping with this limitation in the claims and what is taught in applicant’s specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-10, 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Cho et al. (EP 0774749 A2).

Art Unit: 1655

Cho et al. teaches cosmetic compositions containing hesperetin to enhance keratinocyte differentiation in skin, thus decreasing skin dryness and decreasing appearance of wrinkles (Abstract), in cosmetically acceptable vehicle for the flavanones (page 3, line 13). The invention encompasses a cosmetic method for treating the appearance of wrinkled, flaky, aged or photodamaged skin (page 2, lines 32-33) for human skin (page 8, line 55). Hesperetin is the aglycone equivalent of hesperidin (see Description, paragraph 3, Hesperidin170 (http://170.107.206.70/drug_info/nmdrugprofiles/nutsupdrugs/hes_0295.shtml)). Hesperetin from 0.001-5% weight can be translated to encompass 0.001-5 g.

Claims 17-18, 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Ameer et al. (1996, Clin Pharm Ther, 60, 34-40).

Ameer et al. teaches oral doses of 500 mg hesperidin from grapefruit juice and orange juice, where hesperitin or hesperetin were detected in urine and plasma in man to be less than 25% or less than 25% of 500 mg = 125 mg (Abstract, Methods). Hesperetin is the aglycone equivalent of hesperidin (see Description, paragraph 3, Hesperidin170 (http://170.107.206.70/drug_info/nmdrugprofiles/nutsupdrugs/hes_0295.shtml)). Ameer et al. does not specifically teach using hesperidin to prevent skin disorder. However, the method of preventing skin disorder is considered to inherently teach the claimed method because both the reference and the claimed invention are administering the same composition to the same patient. The patient is the same because every person

Art Unit: 1655

has skin. Thus, on the administration of hesperidin to any patient, a prevention of skin disorder would have had to occur if applicant's invention function as claimed.

Claims 9-12, 14-15, 17-18, 21, 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Bottomley (US 4049798).

Bottomley teaches a method for treatment herpes simplex with Vitamin C and Vitamin P (Abstract) at 200 mg each at one capsule 3 times a day to white male (column 6, lines 60-63). Citrus bioflavonoids, known as vitamin P (column 3, lines 3-4). Herpes simplex is infection of the skin cells (column 4, lines 6-14). Hesperidin is also known as vitamin P (see Description, paragraph 2, Hesperidin 170 (http://170.107.206.70/drug_info/nmdrugprofiles/nutsupdrugs/hes_0295.shtml)).

Bottomley does not specifically teach using hesperidin to prevent skin disorder. However, the method of preventing skin disorder is considered to inherently teach the claimed method because both the reference and the claimed invention are administering the same composition to the same patient. The patient is the same because every person has skin and ages. Thus, on the administration of hesperidin to any patient, a prevention of skin disorder would have had to occur if applicant's invention function as claimed.

Claims 9-10, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyake (EP 0461827 A2).

Miyake teaches ascorbic acid and alpha-glycosyl bioflavonoids effectively promote the growth and regeneration of hair for human and protect scalp from

Art Unit: 1655

ultraviolet (Abstract). Vitamin C and vitamin P exhibit regeneration of hair (page 2, lines 55-57), improves the quality of hair such as hair gloss (page 5, lines 1-2). Hesperidin is also known as vitamin P (see Description, paragraph 2, Hesperidin170 (http://170.107.206.70/drug_info/nmdrugprofiles/nutsupdrugs/hes_0295.shtml)).

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1655

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Examiner Art Unit 1655

/Michael V. Meller/

Primary Examiner, Art Unit 1655